

REMARKS

Entry of the foregoing amendments, favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks.

Rejection under 35 U.S.C. § 102

In the Office Action, beginning at page 2, Claims 1-9 were rejected under 35 U.S.C. § 102(e), as reciting subject matters that allegedly are anticipated by U.S. Patent No. 6,033,433, issued to Ehr *et al.* ("Ehr"). Applicant respectfully requests reconsideration of this rejection.

This application describes devices and methods embodying principles of the present invention. As described throughout this application, and illustrated in the drawing figures, a stent 20, 80 in accordance with the present invention includes S-shaped bridging elements 84, which connect together cylindrical tubes 82. As discussed in the present specification, *e.g.*, at paragraph [0056]:

The bridging elements 84 allow the tissue supporting device to bend axially when passing through the tortuous path of the vasculature to the deployment site and allow the device to bend when necessary to match the curvature of a lumen to be supported. The S-shaped bridging elements 84 provide improved axial flexibility over prior art devices due to the thickness of the elements in the radial direction which allows the width of the elements to be relatively small without sacrificing radial strength. For example, the width of the bridging elements 84 may be about 0.0012-0.0013 inches (0.0305-0.0330 mm).

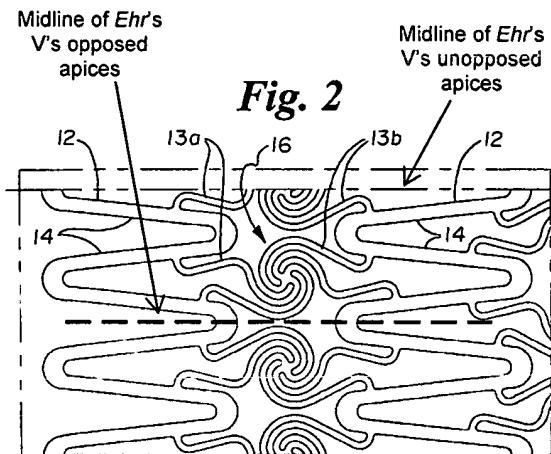
The configuration of the S-shaped bridging elements provides flexibility between the tubes 82 such that the stent can flex in all directions. In addition, the S-shaped bridging elements extend between the V-shapes formed by the interconnected struts which are directly opposed to one another, with the apices of the V-shapes directed at each other (see, *e.g.*, Fig. 4b).

Claim 1 relates to an expandable medical device having a combination of elements including, *inter alia*, a plurality of S-shaped bridging elements connected between interconnected ends of struts in adjacent cylindrical tubes, wherein the bridging elements are

connected entirely above a midline of V-shapes on one cylindrical tube and entirely below the midline of V-shapes on an adjacent cylindrical tube, wherein the bridging elements cross the midline of the V-shapes three times, and wherein said adjacent struts interconnected at alternating ends define an apex for each V-shape, and wherein said midlines connect directly opposed V-shape apices directed at each other.

The prior art, including *Ehr*, fails to identically disclose or describe a device having the claimed combination of elements.

With reference to Fig. 2 of *Ehr*, (reproduced in the Office Action and herein, in differently annotated forms) *Ehr* describes a stent having spiraling structures or coils 16, formed of elongated members 13a,b, interconnecting loops 14 including arguably V-shaped elements (unlabeled). As illustrated in Fig. 2 of *Ehr*, the V-shaped elements each include an apex; because the V-shaped elements alternate in their longitudinal orientation, these apices point in opposite directions for adjacent V-shaped elements in the same loop 14. In Fig. 2 of *Ehr*, adjacent loops 14 have V-shaped elements which point toward each other (through which the midline, added to Fig. 2 of *Ehr*, passes), i.e., are opposed to each other, and V-shaped elements which point away from each other, i.e., include unopposed apices. The other embodiments of *Ehr*'s device are similarly oriented.



As plainly demonstrated herein, *Ehr*'s device's V-shaped elements midlines, for opposed V-shaped elements, do not pass through the elongated members 13a, b at all, because the elongated members 13a, b, and the coils 16 that they form, are laterally (circumferentially) displaced from these midlines. Accordingly, *Ehr* fails to disclose a device that includes each and every limitation recited in the combinations of Claims 1-9.

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 1-9 are not anticipated by *Ehr*, are therefore not unpatentable under 35 U.S.C. § 102,

and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 102.

Rejection under 35 U.S.C. § 103(a)

In the Office Action, beginning at page 4, Claims 10-16 were rejected under 35 U.S.C. § 103(a), as reciting subject matters that allegedly are obvious, and therefore allegedly unpatentable, over *Fischell* in view of *Jang*. Applicant again respectfully requests reconsideration of this rejection.

Claim 10 relates to an expandable medical device having a combination of elements including, *inter alia*, a plurality of S-shaped bridging elements connected between interconnected ends of struts in adjacent cylindrical tubes, wherein each of the bridging elements cross a midline of the V-shapes three times and are connected entirely above the midline of the V-shapes on one cylindrical tube and entirely below the midline of the V-shapes on an adjacent cylindrical tube.

The prior art, including *Fischell* and *Jang*, fails to disclose, describe, or suggest the combinations of elements recited in Claims 10-16.

Fischell describes a device having undulating S-struts 16 intended, according to *Fischell*, to maintain their shape after an initial expansion of the stent. This is so that, if part of the stent obstructs a branching artery, as illustrated in Figs. 4A and 5, another balloon catheter can be pushed through the wall of the stent (Fig. 4B) and expanded (Fig. 4c) to push the S-strut and diagonal struts 14 out of the way (Figs. 4D, 6). According to *Fischell*, this is a very important aspect of his invention.

Fischell teaches away from a modification of his structures such as that proposed in the Office Action. *Fischell* describes undulating S-struts 16 forming expandable cells 12, 12'. The purpose of *Fischell*'s expandable cells 12, 12', to remain expandable after deployment of the stent *in vivo*, is explained throughout *Fischell*:

A second type of cell is designed to provide increased longitudinal flexibility prior, to stent deployment and after stent deployment into a main artery, the second type of cell can be readily balloon expanded at the ostium of a side branch artery to a comparatively

large diameter without breaking any of the struts of the stent cell. By this technique, unobstructed blood flow into the side branch can be provided.

(col. 1, lines 32-39)

a second type of cell provides increased flexibility prior to deployment and after deployment that cell can be balloon expanded into a generally circular shape thereby causing all stent struts to be moved away from the opening of a side branch of a main artery.

(col. 1, lines 45-48)

Therefore as compared to a cell 11', not only is it easier to expand a cell 12' by placing a balloon within that cell and inflating that balloon to a high pressure, but any cell 12' is also expandable to a greater diameter as compared to any cell 11'.

(col. 3, lines 16-20)

Fischell goes on, beginning at column 3, line 23, to describe Figs. 4A-6. In summary, deployment of a stent in the patient's vasculature at the location of a branch artery can partially block that branch artery (Figs. 1, 4A, 5) with the stent itself. Thus, *Fischell* specifically designed his stent structure so that it includes S-struts 16 which remain laterally (circumferentially) expandable after deployment of the stent, so that a balloon can be pushed through the stent's strut structure at a cell 12, 12' (see Figs. 4B, 4C) and expanded to push the theretofore unexpanded S-struts 16 away from the branch artery (Figs. 4D, 6). Thus, *Fischell* teaches strongly away from any modification of his stent's strut configuration which would impair the ability to unblock branch arteries.

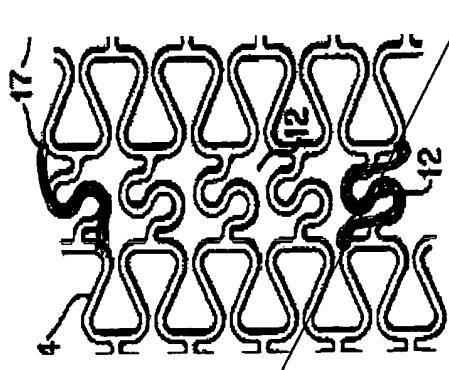
Jang describes (see Fig. 1) a tubular stent 10 including expansion columns 32', 32'', each formed of a set of expansion struts, and connecting columns 34', 34'', each formed of a set of connecting struts. One of *Jang*'s connecting strut sets, connecting together two opposing sets of *Jang*'s expansion strut sets, is reproduced herein. The connecting strut set, formed of struts 66', 68', 74', 72', 70' (see Fig. 2) extend diagonally from one side of one expansion strut set to the other side of an opposed expansion strut set. The reproduction herein of *Jang*'s strut configuration has been annotated with a simple, superimposed line which shows that a midline of

Jang's expansion strut sets crosses *Jang's* connecting strut set only once.

The hypothetical construct alleged to be obvious in the Office Action would, however, destroy the goal of *Fischell's* stent: modification of *Fischell's* undulating S-struts, by replacing them with or modifying them in view of *Jang's*, would result in a stent having limited or no additional expandability after deployment of the stent in the patient's vasculature. The hypothetical combination of *Fischell* with *Jang* therefore would destroy *Fischell's* device's functionality for its intended purpose. Applicant respectfully submits that a person of ordinary skill in the art would not seek to emasculate *Fischell's* stent by modifying it in view of *Jang*.

Assuming, *arguendo*, that the skilled artisan would, despite the fact that *Fischell* strongly teaches away from a combination with *Jang*, look to modify *Fischell's* stent structure with *Jang's* connecting column's strut sets (described above), the resulting hypothetical stent would still not include each and every element recited in the combinations of the pending claims. The Office Action again kindly includes, at page 5, a marked-up portion of figure 2 of *Fischell*, annotated with a

modified S-strut and a diagonal line (reproduced on the right herein). In the Amendment filed 6 January 2006, Applicant



Annotated Fig. 2 of
Fischell, from 6 Jan. '06
Amendment

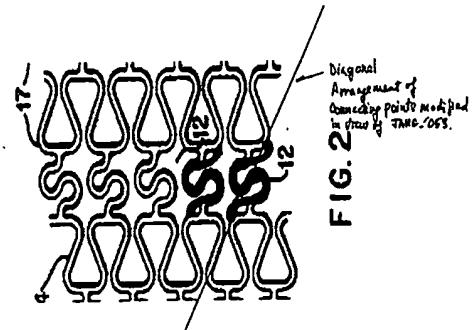


FIG. 2
Annotated Fig. 2 of
Fischell, from 18 April
'06 Office Action

included a reproduction of a marked up version of that illustration, which includes an alternative hypothetical combination of *Fischell* and *Jang* (reproduced on the left herein). Applicant respectfully submits that the illustration contained on page 5 of the Office

Action would not be the stent structure the skilled artisan would arrive at from a full and fair reading of *Fischell* and *Jang*, were the routineer to be motivated to combine the two documents. Instead, the illustration on page 5 is the result of an impermissible hindsight reconstruction of the claimed subject matter using Applicant's own specification as a guide, and therefore a *prima facie* case of obviousness has not been made.

As discussed during the interview conducted 9 December 2005 and in the 6 January 2006 Amendment, were one of ordinary skill in the art to combine *Fischell* with *Jang*, the result would be a *Fischell* stent with, essentially, *Jang* connecting column strut sets. That is, instead of becoming more undulating, as suggested in the page 5 illustration in the Office Action, the result would be a less serpentine S-strut which extends diagonally between *Fischell*'s struts 13, 14 only once, as does *Jang*'s connecting strut sets. Nowhere in *Fischell*, *Jang*, or any other evidence in the record, is there motivation to make *Fischell*'s S-struts more serpentine, and indeed *Jang* specifically teaches away from that configuration by disclosing less serpentine elements. Accordingly, Applicant respectfully submits that a *prima facie* case of obviousness has not been made in the Office Action.

The Office Action states, in response to this line of argumentation, at page 6 thereof:

... the modification as suggested in the previous "Office Action" did not replace a Fischell-'971 S-bridge for a straighter Jang-'053 S-bridge as asserted by the applicant's suggestion. The modification in the previous "Office Action" suggested a modification of the locations of the connections between a Fischell-'971 S-bridge to the struts to modified locations as taught by Jang-'053, this modification will not block a branch artery against Fischell-'971 teaching, but in fact even give more room for cells 12 to expand for a branch artery, because the modified Fischell-'971 S-bridges in view of Jang-'53 are now longer and have more stored length for expansion.

Applicant strongly disagrees.

Jang plainly discloses less-serpentine connecting struts, and thus plainly teaches directly away from the more-serpentine struts that have been grafted onto *Fischell*'s device. The Office Action points to absolutely no motivation in *Fischell*, *Jang*, or any other prior art, and provides no logic, why a person of skill in the art would, upon a full and fair reading of *Fischell* and *Jang*,

make *Fischell*'s connecting struts more serpentine in view of *Jang*'s plain disclosure of less-serpentine struts.

The only source of motivation to make the modification of *Fischell*'s S-struts, alleged to be obvious in the Office Action, is Applicant's own specification, which is an impermissible hindsight reconstruction of Applicant's claimed combination.

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 10-16, each taken as a whole, would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention, are therefore not unpatentable under 35 U.S.C. § 103(a), and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 103(a).

New Claim

Claim 17 has been added as a new independent claim. Claim 17 is based on prior Claim 1, and additionally requires that the adjacent struts interconnected at alternating ends define an apex for each V-shape, and wherein the bridging elements extend between directly opposed V-shape apices in a first of said plurality of cylindrical tubes and said V-shape apices in a second of said plurality of cylindrical tubes. As plainly demonstrated in the annotated version of *Ehr*'s Fig. 2 contained at page 3 of the Office Action, inasmuch as one may consider the elongated members 13a, b of *Ehr* to include an S-shaped portion, that portion extends between V-shaped elements which are not directly opposed. Instead, as plainly illustrated in the Office Action, such an S-shaped portion only extends between the apices of non-directly opposed V-shaped elements. Accordingly, Claim 17 is allowable, an early indication of which is earnestly solicited.

Conclusion

Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of this patent application is therefore respectfully solicited.

If Mr. Bui believes that a telephone conference with the undersigned would expedite passage of this patent application to issue, he is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. If, however, additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to our Deposit Account 50-3100.

Respectfully submitted,

By: 
Cindy A. Lynch
Registration No. 38,699

U.S. P.T.O. Customer Number 43027
1003 Hamilton Court
Menlo Park, CA 94025
650.614.4100

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